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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,372	12/12/2003	Robert Wood Williams III	023868.43877	2530

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BUTLER, SNOW, O'MARA, STEVENS & CANNADA PLLC
6075 POPLAR AVENUE
SUITE 500
MEMPHIS, TN 38119

EXAMINER

STANDLEY, STEVEN H

ART UNIT	PAPER NUMBER
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1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/734,372	Applicant(s) WILLIAMS ET AL.	
	Examiner Steven H. Standley	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9, 10, 12-17, 19, 20 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) 13, 15 and 23-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 10, 12, 16, 17, 19, 20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed 11/06/07 has been made of record. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1-6, 9, 10, 12, 14, 16-17, 19-20 and 22 are currently under examination. Applicant has cancelled 7-8, 11, 18, and 21. Claims 13, 15, and 23-27 are withdrawn.

In spite of the lack of direction as to the basis in the specification for amendments to the claims, there appears to be no new matter introduced into the claims.

Objections/Rejections: Withdrawn

Claim Objections

Objection to claim 21 is withdrawn due to applicant's cancellation of the claim.

Claim Rejections - 35 USC § 112

Rejection of claims 1 under 35 USC § 112 for using a relative term is withdrawn due to applicant's amendment.

Claim Rejections - 35 USC § 102

Rejection of claims 1-3 under 35 USC § 102(b) is withdrawn due to applicant's amendment to measuring pi gsts.

Objections/Rejections: Maintained/New Grounds

Specification

The examiner has objected to the specification for containing hyperlinks. Applicant has neither argued nor amended in this regard. If applicant does not respond to this objection in the following office action, the Examiner will be compelled to consider the amendment as non-responsive.

Claim Objections

Claims 9 and 19 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are drawn broadly to toxins that inhibit oxidative phosphorylation. However, the base claims are drawn to MPTP, which is one species that does such. Therefore, the dependent claim is actually broader than the independent claim.

Claim 22 is objected to because of the following informalities: it is grammatically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Rejection of claims 1-6, 9, 10, 12, 14, 16-17, 19-20 and 22 under 35 USC § 112, 1st paragraph, enablement is maintained for the reasons made of record in the office action dated 8/10/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that the amendments and the declaration by Mr Smeyne overcome the rejection. Applicant is enabled for a method of detecting the changes in GSTpi1 in blood of the disclosed mouse strains. However, Applicant is not enabled for method of detecting the "susceptibility" to environmental toxins, and certainly not by merely measuring the sensitivity of mouse strains to MPTP. The first argument is not found persuasive because, as argued in the prior office action, applicant has enabled the detection of changes in GSTp2 in striatum (as indicated in the last office action) and measuring GSTpi1 protein in mouse blood samples (declaration), but the art and the specification do not indicate the mice are susceptible to anything but the MPTP applicant is using. Moreover it is not clear what they would be more susceptible to. The changes in GSTpi1 are not correlated with striatal cell death, and the changes in striatal GSTp2 are not correlated with the changes in GSTPpi1. What these measurements have to do with susceptibility to anything remains unclear, let alone how the method predicts susceptibility to Parkinson's. Moreover, as made clear in the prior office action the art teaches that GSTPi expression changes with a variety of phenomena that have nothing to do with susceptibility to an environmental toxin or to MPTP, or to Parkinson's disease.

The Declaration filed by Mr. Smeyne has been carefully considered and not found to be persuasive. While the Declaration discloses that incubating whole blood samples from MPTP sensitive strains versus control mouse strains results in decreased relative gstp1 as measure by antibody there is no nexus between the sensitivity to MPTP and any other environmental toxin, which is recited in the preamble. Further, as argued in the previous action, GSTs (including GSTpis) change with a wide range of factors including tissue and environmental stress, pathological conditions such as diabetes, meningitis, and alzheimer's. Little argument can be made that the foregoing are a result of environmental toxins, or toxins that disrupt the electron transport chain.

Claim Rejections - 35 USC § 112

Rejection of claim 1-6, 9, 10, 12, 14, 16-17, 19-20 and 22 under 35 USC § 112, 1st paragraph, written description is maintained for the reasons made of record in the office action dated 8/10/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that the amendments overcome the rejection. This is not found persuasive because the claims are still to a method of determining the susceptibility to an environmental toxin (as recited in the preamble). Further, other claims are still to molecules with no structure and only functional recitations, such as claims 9 and 19. The claims are also to metabolites of MPTP. However, only one metabolite, MPP+, is disclosed by the specification or prior art as being a toxin.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven H. Standley whose telephone number is (571) 272-3432. The examiner can normally be reached on 8:00-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Janet Andre can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

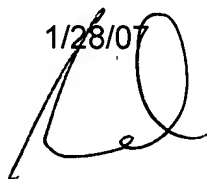
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Steven Standley, Ph.D.

1/28/07


David Romeo
DAVID S. ROMEO
PRIMARY EXAMINER